K023500
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# 510(K) SUMMARY

DEC 13 2002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:
   Innovatech, Inc.
   1F, No. 17, Lane 128, Sec. 1, Chung Shan Rd.,
   Yungho City, Taipei County, Taiwan, R.O.C.

   Contact:
   Ms. Tina Chang
   Product Manager

   Date of Summary Preparation: October 15, 2002.

2. Name of the Device:
   Innovatech Digital Clinical Thermometer, model BABY TEMP / WL-3305 and BABY TEMP(+) / WL-3306.

3. Information of the 510(k) Cleared Device (Predicate Device):
   ACT 2020 and ACT 2020+ (K010238).

4. Device Description:

   The Digital Clinical Thermometers, model BABY TEMP / WL-3305 and BABY TEMP(+) / WL-3306, are the electronic thermometers by using a thermistor as the temperature sensor. The signal of sensor is calculated and displayed by an ASIC (Application Specific IC) – controlled circuit, which is considered the hard-wire control instead of programmable control. Basically WL-3305 and WL-3306 have the same intended use and operation function except for the different measuring range caused by some small different design in IC circuit.

   From the construction point of view, the digital thermometer comprises of a thermistor for measuring sensor, a reference resistor for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

   This system uses a 1.5V DC battery for operation of complete system whenever the battery is low, the ASIC circuit will detect the low battery condition automatically, and displays 'Low battery' in LCD display. Regarding the performance of BABY TEMP / WL-3305 and BABY TEMP(+) / WL-3306, it was designed and verified according to the US standard ASTM E1112-98.

5. Intended Use:

The Digital Clinical Thermometer, model BABY TEMP / WL-3305 and BABY TEMP(+) / WL-3306 are the battery-operated electronic devices with intended use of measuring human body temperature precisely. It can be used in the measurement of oral, axially and rectal temperature.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The Digital Clinical Thermometer, model BABY TEMP / WL-3305 is substantially equivalent to the Actherm model ACT 2020 (K010238), and the Well-life Digital Clinical Thermometer, model BABY TEMP(+) / WL-3306 is substantially equivalent to the Actherm model ACT 2020+ (K010238).

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
Compliance to applicable voluntary standards includes ASTM E1112: 1998, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

8. Conclusions
The Baby Temp series, including BABY TEMP / WL-3305 and BABY TEMP(+) / WL-3306, have the same intended use and technological characteristics as the cleared device of Actherm model ACT 2020 and ACT 2020+. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

Innovatech, Incorporated
Mr. Tony C. S. Chang
C/O Wincent Consultant Company Limited
No. 5, Alley 5,
Lane Cheng Hsing, Chung Ching Road,
Pei Tun Dist., Taichung,
TAIWAN R.O.C.

Re: K023500
Trade/Device Name: Digital Clinical Thermometer/Model: BABY TEMP/WL-3305 and BABY TEMP (+)/ WL-3306
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 15, 2002
Received: October 18, 2002

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

# Indications for Use Statement



510(k) Number (if known): _____

Device Name: Digital Clinical Thermometer / Model: BABY TEMP / WL-3305 and BABY TEMP(+) / WL-3306.

**Indications For Use :**

The Digital Clinical Thermometer, model BABY TEMP / WL-3305 and BABY TEMP(+) WL-3306 are the battery-operated electronic devices with intended use of measuring human body temperature precisely. It can be measurement of oral, axially and rectal temperature.

Valencia Cicconetti

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023500

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ✓

(Optional Format 1-2-96)